

### **REMARKS**

After entry of the instant amendment, claims 1-3, 5, 15, 18-20 and 23-26 are pending. New claims 23-26 have been added.

Support for new claims 23-26 can be found at least at page 1, lines 19-21; page 9, lines 20-26; and page 14, lines 26-28; Examples 3 and 9-11; and original claims 2-4, 7, 9 and 10 of the present Specification. Thus, no new matter has been added by way of amendment to the claims. The Applicant respectfully requests reconsideration of the application in view of the amendments made to the claims and the following remarks.

#### **Rejections under 35 U.S.C. § 102(b)**

Claims 1-3, 5, 15, and 18-20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Breton et al., U.S. 6,019,967 (herein after "Breton").

In the Office Action it is asserted that Breton teaches treating psoriasis with a CGRP antagonist. The Applicant respectfully disagrees.

Breton does not teach the treatment of psoriasis with a CGRP antagonist, but rather discloses that CGRP antagonists may be useful for reducing or avoiding skin-irritating side effects of bioactive agents. Breton seeks to ameliorate the effects of certain skin irritants existing in his compositions like 3-hydroxy acid lotions, acne medicines, and permanent wave solutions. Breton is concerned with making such compositions more tolerable for people with sensitive skin and/or permitting therapeutic, topical compositions with larger amounts of therapeutic skin irritants to be tolerated by users by incorporating a CGRP antagonist.

The Applicant respectfully points out that it would not have been possible for a person of ordinary skill in the art to arrive at the conclusion that psoriasis could be treated with CGRP antagonists by looking at the long list of active agents disclosed in the Breton patent at col. 11, line 27 to col. 12, line 8. Breton states "[i]t is also intended, *inter alia*, to combine the CGRP antagonists with active agents intended in particular for the prevention and/or treatment of skin conditions, complaints and afflictions. Exemplary of these active agents are...", immediately preceding the laundry list of possible active agents. The claimed invention of the present application does not include any of Breton's listed active agents intended to treat skin conditions

other than the CGRP antagonists. In fact, one of ordinary skill in the art could not come to the conclusion to treat psoriasis with CGRP antagonists based on the teachings of Breton.

The Applicant respectfully presents evidence that he had been in contact with several parties (under confidentiality agreements) to discuss drug development of the claimed invention prior to the publication of the Breton patent (issued February 1, 2000), which demonstrates that he was not inspired to develop the claimed invention by reading the Breton publication. (See attached documents memorializing discussions (from as early as June 1998) between the inventor and various others regarding the claimed invention before publication of the Breton patent.)

In view of the discussion above, the Applicant respectfully requests the rejection of claims 1-3, 5, 15, and 18-20 as being anticipated by Breton be withdrawn.

#### New Claims 23-26

Breton only teaches topical or buccal (*e.g.*, in the form of mouthwash or toothpaste) administration of compositions. Breton does not contemplate or teach methods where a composition is applied in any way other than topically or buccally, and therefore does not anticipate methods where a composition is applied dermally, intradermally, subcutaneously, via dermal infusion, via subcutaneous infusion, or via microdialysis, as recited in new claim 24.

Wu et al., Development and potential of non-peptide antagonists for calcitonin-gene-related peptide (CGRP) receptors: evidence for CGRP receptor heterogeneity, *Biochem Soc Trans.*, August 2002, Vol. 30, No. 4, pages 468-473 (hereinafter "Wu"), is cited in the present Specification at page 10. BIBN4096BS was first introduced as a CGRP antagonist to the scientific community in the Wu journal article. The Breton patent issued in 2000, more than two years, before BIBN4096BS was discovered to be a CGRP antagonist. Thus, BIBN4096BS, as recited in claim 24, cannot be anticipated by Breton.

New claim 25 recites a pharmaceutically acceptable formulation consists essentially of a CGRP antagonist and an excipient (*e.g.*, without a skin irritant) to a subject having psoriasis. The pharmaceutically acceptable formulation recited in claim 25 does not include other active agents, such as the bioactive agents required by Breton. Breton does not teach methods including

administering a composition consisting essentially of a CGRP antagonist and an excipient to a subject with psoriasis.

New claim 26 recites methods of treating or remedying psoriasis further comprising exposing the subject to UVB radiation and/or administering a cell division inhibitor to the subject in addition to or in combination with application of a pharmaceutically acceptable formulation comprising a CGRP antagonist. Such methods are not disclosed by Breton.

### CONCLUSION

In view of the above amendment, Applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Stephanie A. Wardwell, Reg. No. 48,025, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated: March 22, 2010

Respectfully submitted,

*for* By Stephanie A. Wardwell, #48025  
MaryAnne Armstrong  
Registration No.: 40,069  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Road  
Suite 100 East  
P.O. Box 747  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicant

Attachment: Documents memorializing Applicant's discussions regarding the claimed invention before publication of the Breton reference.